

# EXHIBIT H

MEDIA ID: STERIGENICS-HEARING-3.MP4

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SARD VERBINNEN & CO

ILLINOIS SENATE HEARINGS

ENVIRONMENT AND CONSERVATION COMMITTEE HEARING

CHAIR: SEN. DAVID KOEHLER

PANEL 1: JEN WALLING, JEAN HOLHALTER,

URSULA TANNAWAY

PANEL 2: DONOVAN GRIFFITH (IMA), BRAD BABCOOK,

DR. JANE TATA, THOMAS TRIMBLE

SPEAKERS: SEN. JOHN CURRAN, SEN. MELINDA BUSH,

DIR. ALEC MESSINA (IEPA)

PRODUCER: (NOT IDENTIFIED)

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\* \* \*TRANSCRIBER'S NOTE: BACKGROUND NOISE THROUGHOUT; ONLY TRANSCRIBED IF PARTICULARLY INTRUSIVE. COMMITTEE MEMBERS REFER TO ONE COMPANY AS VANGUARD UNTIL SEN. BUSH IS CORRECTED WITH VANTAGE ON PAGE 110. \* \* \*

ON-SCREEN TEXT:

00:00:00;06 Illinois Senate Environment and Conservation  
Committee Hearing

SEN. DAVID KOEHLER, CHAIR:

00:00:00;13 (IN PROGRESS) --here's what we're gonna do in the  
subject matter hearing. We're gonna ask-- Senator  
Curran to make-- an opening statement. We'll ask-

- Senator Bush-- please add Senator Bush to the roll. We'll ask Senator Bush to-- also make an opening statement. And then we're gonna have three panels-- the first-- representing environmental concerns-- and residents of the affected areas.

00:00:23;04

Secondly, we'll have-- people representing the industry-- talk. And then third, we'll have-- Director Alec Messina from EPA-- give some remarks. Please add Senator Morrison to the-- roll. And-- during the-- after-- after the panels-- each panel-- makes testimony, then-- I will open it up for questions from the-- committee. We're asking each panel to-- keep your remarks within-- a ten-minute-- timeframe-- so that we can try to-- get through this-- expeditiously as possible. We are not going to take any action on this. This is a subject matter hearing only. So, Senator Curran, welcome.

SEN. JOHN CURRAN:

00:01:05;15

Thank you, Mr. Chairman. I want to thank all the

members of the committee this morning for your-- time and attention on this very-- important matter, not only in my district, but-- throughout the state of Illinois. I-- I want to tell you, back in late August-- when the U.S. EPA notified the village of Willowbrook about-- heightened-- heightened concerns that they had with the-- emissions coming from Sterigenics-- related to ethylene oxide, a compound that's used to sterilize-- many products-- including-- surgical equipment.

00:01:44;01

The village of Willowbrook, the surrounding communities have really become paralyzed in fear. I mean, we are talking health, safety of the most vulnerable in our population. And we-- we-- we currently-- the more you dig into this, you realize that this is-- very scary stuff and this is-- you know-- a great public concern.

00:02:07;12

You know, I-- I do-- want to compliment the-- Illinois Department of Public Health, who has

come in to do a-- cancer study in an expedited manner on this c-- in-- in this area. And that's gonna be completed-- we hope by the beginning of March. I have worked-- with the Illinois Environmental Council, with-- Senator Bush-- on some proposed legislation.

00:02:32;08

You have two pieces of legislation before you-- this morning-- as-- as we begin to work on this product-- work on this topic and try to really dig in and-- determine what, if any-- levels of-- or emissions of ethylene-- oxide are appropriate in our communities. The legislation-- I've put forward-- contemplates-- no emissions of ethylene oxide by 2022 in the state of Illinois as-- this is not a-- a safe-- toxin to be released into the air-- being that it is a known carcinogen. So, I-- I think you for your-- your time and attention this morning. And I know you have-- several panels-- that are gonna come up and provide further context. So, thank you, Mr. Chairman.

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SEN. DAVID KOEHLER, CHAIR:

00:03:21;18 Thank you. Senator Bush?

SEN. MELINDA BUSH:

00:03:25;16 (NOISE) Thank you very much-- Mr. Chairman. Thank you, Senator Curran. This-- issue really expanded lately. And certainly not that it isn't a large enough problem-- in the district that Senator Curran represents-- it is-- you know, we are now aware that both-- Vanguard and Medline-- in Lake County-- are emitting-- ethylene oxide.

00:03:49;14 What we need to get at is is there a safe, acceptable level, what that is-- and make sure that, first of all, public safety is the priority. You know, it has to be the priority going forward-- but we also have to understand-- I mean, I, you know, feel like this is-- I'm really happy to be here today. There's a lot to learn-- about ethylene oxide.

00:04:15;17 And I-- I think there's just gonna be a lot of questions. I'm really happy to be working with

Senator Curran. I called him immediately-- and signed onto his bill. I'm happy to provide any support to move that bill forward. This will be a-- bipartisan effort-- to do what is right-- for the people that live in the state of Illinois. So, thank you.

SEN. DAVID KOEHLER, CHAIR:

00:04:36;28

Thank you very much. So, would the first-- panel please come up and-- take your seat? I'll have you introduce yourself. Again, for the committee-- we're asking each panel to-- take ten minutes-- make their remarks, and then we'll open it up for any questions that you might have. So-- welcome, panel, and please introduce yourself.

JEN WALLING:

00:04:55;26

Good morning. My name is Jen Walling. I'm the executive director of the Illinois Environmental Council. And I am going to be very short because I'd like Ursula and Jean, who are local residents, to be able to offer their testimony and personal experience with this.

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00:05:09;18

But I'll just say I know all of you know me from being in front of this committee many times, but in addition to being an issue that I care deeply about-- preventing cancer in Illinoisans-- I grew up in Deering, Illinois, less than two miles from this facility, at a time where it was emitting ten times the ethylene oxide that it is today, and my mother had a breast cancer when I was a child.

00:05:31;13

And I can't tie my mother's cancer to this particular facility-- but we do know that ethylene oxide does cause cancer at such a rate that no level ex-- of exposure has been identified as safe. This bill that's been presented today, Senate Bill 3640, that we worked with Senator Curran to draft, is also a compromise.

00:05:52;06

It's not something that bans ethylene oxide emissions immediately. And we know that that's what the folks who live in the community-- both



in DuPage and Lake County, want to see because that is the safe level-- of ethylene oxide. So, what we are already presenting, the phase out that we're working at is-- is already presenting a compromise, but we understand that local folks want this banned-- immediately.

00:06:16;23

The bill that Senator Curran's put together is-- a phase out in different approaches that we can, if you have questions-- you know, to-- be replaced by other alternatives. But it also includes really important provisions, and I-- think when other speakers are up, you should ask questions about this-- to give the IEPA overall tools to reopen air permits when there is a public health hazard, because that's been one of the issues that's happened today.

00:06:43;21

This type of issue could happen in any of your districts, at any time, and we would be unable to reopen air permits to adequately address the issue quickly. And that's what Senator Curran's

bill-- does and why it's very important to this issue statewide. So, I'll let these speakers-- from the community address the issue.

SEN. DAVID KOEHLER, CHAIR:

00:07:03;18

Yes, and please identify yourselves.

JEAN HOLHALTER:

00:07:05;28

Hello, my name Jean Holhalter (PH). I grew up in Burr Ridge, Illinois, which is an adjoining town to Willowbrook. I currently live in Naperville, Illinois. In 2001-- or I'm sorry, in 2011, I was newly remarried. My son was prospering in high school and life was just looking absolutely fantastic. It was very exciting.

00:07:27;18

But in August of 2013, we were dealt a very brutal blow. A piece of paper delivered my fate, invasive aggressive lobular ductal carcinoma. Please close your eyes for a minute and imagine your child or small child that you love, and having to tell them that you have cancer. This is a child I raised on my own. We did not know for some torturous time whether I would live or

whether I would die.

00:08:03;13

I didn't know if I would get to see my son graduate from high school, select a college, graduate from college, get married, have a child. Those were all my big (UNINTEL) in life. That's what I-- that's what I wanted. I have no family history of cancer. I do not carry the BRCA gene or genetic mutations. There was no reason for me to have breast cancer.

00:08:28;29

I did, however, breathe in the toxic emissions of ethylene oxide, which Sterigenics had willfully and is still spewing out into our community at time-- at rates that are unacceptable. I lived in Burr Ridge from 1967 to 1992, living, working, and attending school all within a one-mile radius of this company. I was breathing in toxins, we didn't even know how much. My parents believed I was safe while growing up. That's-- that leant itself to be very untrue.

00:09:04;15

The real harm from ethylene oxide comes from long-term and chronic exposure. Until recently, I did not know the extent of the damage ethylene oxide had potentially on my life. Back in 1995, I was so excited to have my first baby. We chose names. We bought baby clothes, prepared for-- for parenthood with great excitement. I lost my first baby due to fetal abnormalities for unknown reasons and did not know if I could have a healthy child.

00:09:39;02

Until-- until recently, I did not know the extent of the damage from ethylene oxide, until I looked (LAUGH) back in August, I-- I looked at the list of all of the issues that ethylene oxide produces-- and medical issues, and we just checked 'em off one by one. It was so scary, so sad, and I became very angry.

00:10:04;06

Eighteen years later, after my miscarriage, we received the news of my breast cancer diagnosis. Hearing the word cancer changes your life in

unimaginable ways, and ways that you can't imagine until it happens to you. My potential killer is faceless, odorless, tasteless. It's very explosive, because ethylene oxide is very explosive, and it has a name-- ethylene oxide.

00:10:32;01

My body was ravaged by a double mastectomy. I am permanently disfigured. The physical pain I have endured is more than most people can imagine. The mental anguish that has accompanied my cancer diagnosis has been through the roof. From the day of my diagnosis forward, I have struggled with P.T.S.D., anxiety, and my body is almost always in fight or flight mode. However, it's-- it's very-- a horrific way to live, not knowing if you're going to get cancer again. That thought is always there, always there. You can never escape it.

00:11:11;07

Every day, that's my reality. That's how I have to live. Going through chemo, I lost my hair, I lost my eyelashes, I lost my eyebrows, I lost my

mojo, and I lost my dignity. Since 2013, I've had about 15 major surgeries, with many more to come. Additionally, I've suffered from chronic up-- upper respiratory, reproductive, and GI issues since about 1984 or '85, which coincidentally is when Sterigenics came to town.

00:11:45;15

In August of this year, like I said, I was horrified to read the list of all of the issues. And I'm-- one example of the prolific number of cancer victims in our area. There are children fighting for their lives because they have developed leukemia, lymphoma, and other cancers. How many lives have to be lost to this killer?

00:12:08;23

EtO sterilization firms are not philanthropic organizations. They are for-profit companies that reap financial benefits while they cause billions of dollars in damage-- to public health and loss of property. When are the EPA and those who condone the usage of ethylene oxide in a highly concentrated residential area and community going

to be held accountable? These beads are called the beads of hope. This little girl is a community member, okay. She's holding her beads of hope.

00:12:49;18

This represents about 1,000 of 'em, okay. It's 24-feet long. This girl had over 5,000 of 'em when she stopped counting. This little girl, again, this little boy should be down at-- at-- I think Alabama, Roll Tide. He's at home now. He can't work, go to school, or anything for a couple of years because he has leukemia, lived in the-- area for a long time. This poor lady lived in the area for a long time. She has-- has-- cancer. You know, here I am after breast cancer. And here's this little baby, innocent, didn't do anything wrong, okay. She has cancer.

00:13:48;15

I implore you, on behalf of the large number of cancer sufferers, their loved ones, and those suffering from a myriad of-- serious health issues attributed to ethylene oxide in Illinois,

ban ethylene oxide usage. There is no safe amount. People will come in here and tell you there are safe amounts and that they're in compliance. There is no safe amount. Zero.

00:14:16;06

This should be a zero tolerance. You have the power to make the changes, to save our lives. Do not allow companies to profit on the backs of the children and people they are harming and killing. And they are harming and killing us. (SIGH) How many more people have to suffer mentally and physically before you, our legislators, make laws banning the toxic use of EtO? The public has more of a right to breathe clean air, live their lives without fear, than Sterigenics and companies using EtO have to make a profit at our community members' expense. Needles, syringes, tubing are all disposable. Children and humans are not. Do right by your constituents, please. Human safety over profits, it's the only conscionable decision you can make. Thank you.



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SEN. DAVID KOEHLER, CHAIR:

00:15:26;18 Thank you. And--

URSULA TANNAWAY:

00:15:30;17 Good morning. And thank you for--

SEN. DAVID KOEHLER, CHAIR:

00:15:31;27 Your name? Your name, please?

URSULA TANNAWAY:

00:15:34;11 My name is Ursula Tannaway (PH). Thank you for providing us the opportunity to participate. I'm a member of Stop Sterigenics Movement-- that formed when we found out that ethylene oxide was being spewed into our community. My family has lived in the surrounding area since 1989.

00:15:53;09 Today, I'd like to talk about some numbers and what we can do about them. Ethylene oxide is a potent human carcinogen. It always has been. To echo Dr. Susan Buchanan's assertion at the General Assembly committee hearing on October 26th, there is no safe level of exposure to a carcinogen.

00:16:12;04

We think about exposure in terms of acceptable risk. According to the EPA, the acceptable risk for a single carcinogen is one incidence of cancer in one million people. At 100 in a million, action is considered. In 2016, 24 specialists and 14 government agencies or divisions worked together to update the way the EPA calculates the health risk associated with ethylene oxide to better match the current scientific understanding.

00:16:43;11

These are people whose interest is public health and safety. Bear with me, I'm gonna give you some numbers. I've converted the units to make them easier to compare in case you've been reading about ethylene oxide and see some zeroes in different places and some different units. The concentration of ethylene oxide that is calculated to give a one in a million estimate-- (BACKGROUND VOICE) sure, I'm gonna flip through them-- is .2 nanograms per meter cubed.

00:17:12;12                   One hundred in a million is 20 nanograms. The NIOSH Recommended Exposure Limit is 180 nanograms, time-weighted average for an eight-hour work day. OSHA's limit is 1,800 nanograms, time-weighted average for an eight-hour work day. Both recommend limits of 9,000 nanograms, for a maximum of 15 minutes per day.

00:17:37;15                   These values assume workers are only exposed at work, under controlled conditions. They also factor in the ability to measure exposures at those levels. According to self-reported stack emissions data from Sterigenics for 2014, when they claimed to have been operating at a 99% emissions reduction rate, the Nada (PH) models estimate a maximum air concentration of-- have I got-- do I have the right one? Of 76 nanograms near Sterigenics.

00:18:11;00                   That corresponds to a cancer risk of between 250 and 350 per million, depending on whether you use the raw or adjusted estimate. In May 2018, the

measured amounts in residential areas near Sterigenics were as high as 2,100 nanograms per meter cubed. In the office park, a measurement of 9,100 nanograms was recorded. In June, Sterigenics updated their controls and tested them in September.

00:18:40;26

In October, a nearby private company measured an indoor ethylene oxide concentration of 1,700 nanograms. Why is there such a discrepancy between estimates based on stack data and measured concentrations? Something isn't right. Our community members have been reporting many symptoms that support the measured ambient air amounts. Several children in pro-- in close proximity to Sterigenics have had tumors removed or are cancer survivors, elementary school children.

00:19:14;23

Adults and children report chronic headaches, gastrointestinal distress, respiratory disease, eye irritation, multiple miscarriages, and of

course cancers. Emissions have not-- emissions controls have not kept our community safe or healthy. We've known for decades that there are significant health risks associated with exposure to ethylene oxide, including, but not limited to cancers.

00:19:38;15

Industry is arguing about how much additional poison is okay for our families, our children to breathe. We've seen this before with lead, with asbestos, with smoking. It's time we change the way we think about these substances. It's time to stop thinking about how much risk is acceptable, how many loved ones we lose to acceptable risk. It's time to start justifying why using ethylene oxide is actually required and to relocate facilities that do this away from densely pop-- populated areas and notify any residents in those new locations.

00:20:16;20

SB-3640 tries to do that. It asks industry to take a good, hard look at why they're poisoning

people and make real progress to switching their supply chain to alternative methods. Hospitals across the U.S. have been doing this for years. It's time we push the supply chain to switch, too, because they won't switch from this artificially cheap method or move their operations until we force them to. Thank you.

SEN. DAVID KOEHLER, CHAIR:

00:20:45;13

Thank you both for your testimony. We'll take a few minutes to see if there's any questions-- Senator McGuire? Would you please add-- Senator Biss to the roll? Senator McGuire?

SEN. PAT MCGUIRE:

00:20:57;06

Thank you, Mr. Chair. Thank you to all three of your-- for your testimony. And Senator Curran, you mentioned that there's an IDPH cancer study that's due in March. Have there been any-- epidemiological studies done in the past by any state or federal agency?

SEN. JOHN CURRAN:

00:21:15;16

For this particular area, no, Senator.

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SEN. PAT MCGUIRE:

00:21:18;23                    Okay. And Jen Walling, you mentioned that ste--  
Sterigenics once emitted ten times the present  
level of EtO. What caused the reduction?

JEN WALLING:

00:21:31;16                    So-- and I am-- I've got some of those numbers on  
it from the '80s. Some of it was increased  
emission standards-- over time. So-- and we, even  
in this past year, there have been increases in--  
in the permit-- or decreases in what they're able  
to emit by their permit.

SEN. PAT MCGUIRE:

00:21:47;25                    Are those fed-- are you talking about federal EPA  
levels?

JEN WALLING:

00:21:50;09                    Yes.

SEN. PAT MCGUIRE:

00:21:50;11                    Illinois EPA levels?

JEN WALLING:

00:21:52;09                    Federal.

SEN. PAT MCGUIRE:

00:21:53;06                    Okay. And has there been any enforcement action,

any fines, any cease and desist orders ever  
against Sterigenics?

SEN. JOHN CURRAN:

00:22:04;15

In 2013-- there was action taken by the Illinois  
attorney general and the Illinois EPA-- with  
regards to-- ethylene glycol, which is--  
antifreeze-- a large leak. And they also had-- a--  
- a-- an unscrubbed emission of-- of ethylene  
oxide-- into the air at that time as well-- and  
they were-- ultimately they were fined in 2015  
through the-- process-- after filing in-- circuit  
court of DuPage County.

SEN. PAT MCGUIRE:

00:22:35;00

So, in 2015, Sterigenics was fined by the federal  
EPA?

SEN. JOHN CURRAN:

00:22:39;21

No-- Illinois EPA.

SEN. PAT MCGUIRE:

00:22:41;02

Oh, Illinois attorney general for an excessive--

SEN. JOHN CURRAN:

00:22:43;00

Illinois attorney general, yes, for--



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SEN. PAT MCGUIRE:

00:22:44;01 Excessive emission of EtO?

SEN. JOHN CURRAN:

00:22:45;11 Emission and also a toxic spill-- in the-- in--  
in the ground as well. And I-- I-- if I could  
very quickly--

SEN. PAT MCGUIRE:

00:22:52;09 Yeah.

SEN. JOHN CURRAN:

00:22:53;20 --add-- the Illinois EPA and the-- DuPage County--  
- Health Department recently announced that  
they're gonna be testing all the-- they're gonna  
be doing water well-- test samples in the area as  
well.

SEN. PAT MCGUIRE:

00:23:05;24 Thank you. And-- workplace exposure-- exposure  
inside the plant? Is there any record of OSHA  
inspections, OSHA enforce-- enforcement, NIOSH  
health hazard evaluations?

00:23:18;07 (OFF-MIC CONVERSATION)

JEAN HOLHALTER:

00:23:27;21 Sterig-- well, let me go back. Sterigenics has--

a history of many violations across the world, and many ex-- factory explosions. As far as OSHA, we're still studying that. We're-- we're highly looking into this. So-- and I think Ursula has a scientific background, I believe, so you know, we're-- we're studying this. We're trying to get the information.

URSULA TANNAWAY:

00:23:53;16

We'll-- we'll-- we'll get you what information we can-- about OSHA violations, if there's more to get you.

SEN. PAT MCGUIRE:

00:23:58;11

Okay. Do employees at Sterigenics belong to a union?

JEN WALLING:

00:24:02;27

So, I'm not sure at the particular facility, but we do know that some of the SCIU healthcare workers are impacted by ethylene oxide emissions because they work in some of the facilities that do this and-- and have to-- you're given a lot of precautions if you're working with ethylene oxide in-- in a hospital or other facility.

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SEN. PAT MCGUIRE:

00:24:22;24                    Okay. And Ursula, I appreciate the information you gave us about-- the NIOSH recommended TLB and OSHA's concern-- current TLB (UNINTEL) or those-- those are eight-hour time-weighted averages, right? So, I noticed that NIOSH's recommended eight-hour TW-- yeah, time-weighted average is 1/10 of the current OSHA standard.

URSULA TANNAWAY:

00:24:44;12                    Yes.

SEN. PAT MCGUIRE:

00:24:45;00                    Which indicates that research suggests that the OSHA limit should be reduced.

URSULA TANNAWAY:

00:24:50;25                    Yes. And this is not recent. This was-- I don't even remember the year. It was late '90s, early 2000s. This has been a standard by NIOSH for a long time.

SEN. PAT MCGUIRE:

00:25:01;27                    Okay. And-- correct me if I'm wrong, so it's not a standard; it's a recommendation.

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URSULA TANNAWAY:

00:25:05;24 It's a recommendation officially.

SEN. PAT MCGUIRE:

00:25:07;05 Okay. Well-- is there a separate-- separate from the NIOSH recommendation and the current OSHA standard, is there an EPA standard for extramural emissions?

URSULA TANNAWAY:

00:25:22;22 As far as I've been told, there are no standards for ethylene oxide emissions. There are recommendations. But somebody more versed in regulations should probably speak to it than I.

SEN. DAVID KOEHLER, CHAIR:

00:25:35;19 We will have Director Messina--

SEN. PAT MCGUIRE:

00:25:36;26 Okay.

SEN. DAVID KOEHLER, CHAIR:

00:25:37;29 --at the very end, so--

SEN. PAT MCGUIRE:

00:25:38;07 All right. Thank you. And-- oh, Jen, you mentioned-- you advocate a phase-out of EtO and that it be replaced by alternatives. Are there

alternatives?

JEN WALLING:

00:25:49;06

Yes. And I can give you-- you know, there's actually-- some information that's been compiled by physicians on the different alternatives. And we have had some discussions-- I mean, I think they're gonna talk today. You know, the Hospital Association-- I-- I hope I'm not speaking out of turn, and they'll give this information, that-- the hospitals themselves are typically just using ethylene oxide canisters and they have been working on phasing that out and feel like they need a time period.

00:26:16;24

But in hospitals, they feel like they can phase out ethylene oxide usage there. They have alternatives that they're using for the in-hospital sterilization. And we feel there are a number of-- alternatives that can be used-- for the type of equipment. You know, a lot of this may be-- you know, metal can have a different type of sterilization, it's my understanding,

than, like, rubber or plastic.

00:26:42;12

So-- there are numerous alternatives that can be used. I mean, of course, for the plants themselves, that's going to be-- a costly turnover to create those alternatives, but-- for something that is safer. So, there are-- there's copious alternatives. We've proposed a phase-out that-- bans it by 2022, but we know, you know, the residents locally want this shut down immediately.

SEN. PAT MCGUIRE:

00:27:08;20

All right. Thank you.

URSULA TANNAWAY:

00:27:09;20

And if I could add-- we know of several hospitals in the area that have voluntarily discontinued all use of ethylene oxide on their premises. One is St. Anthony's and another is Swedish co-- Covenant. And those are both in the Chicago area. There were a few in California that we read about that have also done so.

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00:27:31;02                   And they have replaced them with equivalent alternatives-- that they've seen a lot of benefits because the cycle times are faster, the-- the emissions are non-toxic. They're water vapor, carbon dioxide. So, this has been done in hospitals in the U.S.

SEN. PAT MCGUIRE:

00:27:49;05                   Thank you.

SEN. DAVID KOEHLER, CHAIR:

00:27:50;05                   Dave Dahl (PH) requests-- being able to take photographs. Without any objection, we'll grant that. Senator Oberweis?

SEN. JIM OBERWEIS:

00:27:57;04                   Thank you, Mr. Chairman, and thank you to all of you for taking the time to-- to testify here this morning. I think a lot of us believed or hoped that-- this kind of stuff doesn't happen in the United States anymore, but obviously that's-- not a good-- assumption. I just-- I just have a couple of quick questions. First of all, is this a public company, do you know? Sterigenics? Or is it a private company?

JEAN HOLHALTER:

00:28:22;01 Right now, it's a privately held company. They  
did try to go public at one point and they  
withdrew their SEC--

00:28:29;05 (OVERTALK)

SEN. JIM OBERWEIS:

00:28:29;20 I can see why.

JEAN HOLHALTER:

00:28:30;06 Yeah, I can see why as well.

SEN. JIM OBERWEIS:

00:28:34;29 Secondly, do we know-- were they invited to come  
here-- and-- and present some-- some--

SEN. DAVID KOEHLER, CHAIR:

00:28:41;04 Yeah, there's--

SEN. JIM OBERWEIS:

00:28:41;07 --opposition argument or case?

SEN. DAVID KOEHLER, CHAIR:

00:28:42;14 They're up-- they're up next.

SEN. JIM OBERWEIS:

00:28:43;22 They are here?

SEN. DAVID KOEHLER, CHAIR:

00:28:44;02 Yes.



SEN. JIM OBERWEIS:

00:28:45;07                   Okay. I think the last question I have is-- do we have an idea of how far this-- could affect people? I mean, is this something that affects people within a quarter of a mile or a mile or three miles or--

JEN WALLING:

00:29:01;27                   So, that's very interesting. As I mentioned earlier, when the-- the NATA report-- produced an interactive map. It's really cool. You can go in there and move around and find your particular address. You can look around at your neighborhood. You can zoom out and see regional things.

00:29:21;04                   And using the self-reported stack test data, so s-- Sterigenics reports an amount that they expect that they've emitted-- the NATA report calculated a concentration that was on the ground and then extrapolated some-- or calculated the health associated risks. The splotch on our map is huge. It cover-- covers several square miles.

And it trends with the winds toward the northeast.

00:29:49;21

So, that number that I gave earlier, this one, is what Sterigenics reported. The number that was measured in May of this year and in October is this one on the ground. So, there-- there is something wrong here. Either the-- I'm sorry, I'm (UNINTEL) all over here. Either the-- the stack reporting is incorrect or the air modeling is incorrect or these measurements are incorrect.

00:30:23;17

I tend to think it's this number that's incorrect because we have the biological data of people who are on the ground, affected by these emissions, that support symptoms that fall within this range if you look at symptoms that are associated with various concentrations in the workplace. So, we already know what kind of things are associated with high-- higher level emissions and they're matching.

SEN. JIM OBERWEIS:

00:30:48;25

Thank you very much. And-- I'm sorry, one last quick question. You mentioned St. Anthony, but I didn't hear what you were saying about that, and I have a daughter who's a nurse at St. Anthony. Could-- could you just tell me what that was in regard to?

JEN WALLING:

00:30:58;21

So, at-- since-- there were two hospitals that were named in supplemental data. If you-- go into-- the NATA report is huge and they talk about ethylene oxide emissions all over the region. The big splotch is ours from Sterigenics, but there are also some smaller point sources. And those, if you scroll over them, they're mostly hospitals.

00:31:20;03

One of the things that they noted in their supplement, because this data was taken in-- from 2014 reports, is that in late 2014 and in 2015, there were two area hospitals, St. Anthony's was one of them, Swedish Covenant was another, that

voluntarily discontinued their use. So, what comes up on the map as this cancer risk in those areas should be modified because they no longer use the ethylene oxide they-- they reported in 2014.

SEN. JIM OBERWEIS:

00:31:46;21 Thank you. Thanks very much.

JEN WALLING:

00:31:48;07 Sorry, long story short.

JEAN HOLHALTER:

00:31:49;11 May-- may I make one comment about the dispersion? In Lisa Madigan's complaint against Sterigenics, she mentioned a Whitaker Park. That is literally right next door to my parents' house. So, you know, that's a mile as the crow flies. And my legal team has said that, with their dispersion experts, it goes far beyond. So--

SEN. DAVID KOEHLER, CHAIR:

00:32:13;20 All right. Thank you very much to this panel. The next panel-- represents-- I don't-- I'm not sure that Sterigenics is-- represented in--

specifically, but there are people from the industry that are gonna be-- testifying. So-- will the second panel please-- come up.

00:32:29;29

Since we took about-- 25 minutes with-- questions-- from the committee as well-- we'll try to-- be fair to-- this panel as well. About half that time will be used for your testimony and then we'll open it up for-- additional questions from the committee. So, please-- identify yourself as you speak.

DONOVAN GRIFFITH (IMA):

00:32:49;09

Thank you. Thank you. My name is Donovan Griffith. I'm the director of government affairs for the Illinois Manufacturers' Association. I'll be very brief 'cause we actually have experts herewith us today, especially an expert-- in EO or EtO-- however you look at it, for ethylene oxide.

00:33:04;28

As it stands right now, the Illinois Manufacturers' Association is opposed to Senator

Curran's two bills. We do not believe that a ban of ethylene oxide is necessary. The science that has been used to get us to this point in the U.S. EPA reports and in their risk assessments is flawed. They, themselves, in doing the reports, have admitted to assuming a lot of data. The risk level set for ethylene oxide is flawed, as it was taken out of those reports.

00:33:31;08

So, we do not believe a ban of ethylene oxide is necessary. So, as it stands, we-- we are also-- we have had one stakeholder conversation with Senator Curran-- yesterday. I believe there are more to come. So, while we are opposed to the two bills, we do-- look forward to working with him and continuing those conversations.

BRAD BABCOOK:

00:33:50;17

Thank you, Donovan. Thank you, Mr. Chairman and members of the committee. I'm Brad Babcook, on behalf of the Chemical Industry Council of Illinois. Before turning this over to-- to Dr. Tata and Mr. Trimble here to discuss the science

and what some perceive as alternatives, I just want to make a few brief-- yeah, I just wanted to make a few brief-- remarks.

00:34:08;24

Aside from the 1% of ethylene oxide that's actually used in the sterilization, the rest is used in-- a whole host of different manufacturing-- processes-- that-- that my members use. Some are at non-detectable limits. And I have even one-- member in-- in particular that doesn't even emit this into the atmosphere.

00:34:27;13

This bill would actually ban all uses of that immediately. So, I just wanted to reiterate-- Donovan's comments to that. You know, we-- continue to-- talk with, you know, meet with the-- with the sponsors of the bills, both in the House-- House and the Senate, and see if there is-- is some type of common ground-- that can be reached. But-- but with that, I think it's really important really to kind of focus this discussion now on the actual science and-- like I said, what

some perceive as-- as-- as alternatives. So, with that, I can turn it over to Dr. Tata.

DR. JANE TATA:

00:34:58;10 Good morning. My name is Jane Tata. I'm--

SEN. DAVID KOEHLER, CHAIR:

00:35:01;05 Can-- can you speak right into the microphone so everybody can hear? Thank you.

DR. JANE TATA:

00:35:04;24 I am a principle epidemiologist at Exponent, a scientific con-- consulting company based in Menlo Park, California. I received both my master's and doctoral degrees from Yale University, where I majored in biostatistics for my master's and chronic disease epidemiology-- for my doctorate.

00:35:25;13 I've been an occupational epidemiologist for 40 years, 35 years of which I have focused extensively on ethylene oxide, both conducting research studies and risk assessments and working with government agencies. I've been on the ATSDR Board of Scientific Counselors for four years.



I've been on the EPA-- I've been a consultant to the EPA Scientific Advisory Board, and many other associations with government scientists.

00:35:57;02

I'm here at the request of Medline, to offer my opinions regarding the findings of ethylene oxide worker health studies and how and why these findings are contrary or inconsistent with the U.S. EPA ethylene oxide cancer assessment. I just want to clarify that the ATSDR report that you heard about, the NATA report that you heard about, the foundation of those two reports are this EPA cancer risk assessment. And that's the focus of my comments.

00:36:32;26

And I thank you for the opportunity to be here today, to hopefully clarify some of these scientific issues. Let me jump to the main point of my remarks. The EPA risk assessment is flawed and it should not be used as it has been used to predict cancer risks of any kind. I'll outline three reasons why I hold this opinion. The EPA

report that calculated this risk assessment was based on a faulty exposure response model.

00:37:05;29

By that, I mean the agency has to try to model data showing the relationship between exposure and risk. It is my opinion they have a faulty model for doing that. And we'll talk a little bit more about that. In addition, the EPA used the NIOSH study exposure estimates for workers that were-- were estimated implausibly lower in the early years of the sterilin (PH) industry.

00:37:37;19

NIOSH study estimated exposure in the early years where there was no data. And their estimates show higher-- lower levels in the early years. Really, that is not-- plausible. We know-- everything we know is that exposures were higher in the early years. In addition, the report used only one study in their statistical analysis and they ignored contradictory research. And I'll talk a little bit more about that.

00:38:08;12

Now, let's focus on what-- what have we learned from human studies of ethylene oxide workers? There are a large number of studies published over a 40-year period in the U.S. and in numerous European countries. There is no pattern of increases for any type of cancer among the 13 studies, which included over 34,000 ethylene oxide workers, both in sterilin operations and in manufacturing.

00:38:39;16

And isolated increased risks seen are of small magnitude and based on small numbers. And there is no-- and this is very important, there is no clear increase in risk with greater exposure. That is a pattern you look for with a carcinogen. More exposure, more risk. The limited human evidence-- limited in the sense of evidence of carcinogenicity, and the one relied on in the EPA and their assessment, comes from a large study of sterilin workers conducted by the National Institute of Occupational Safety and Health, NIOSH.

00:39:19;29

The evidence of cancer risk was limited and the conclusions of the study authors were not definitive. The NIOSH worker communication, after the completion of their study, noted that their suspect findings of increased risk were related to, and I quote, "very high levels of EO exposure which existed over 40 years ago, before current safety practices and exposure limits were implemented."

00:39:51;03

The other most informative EO worker study, and one of the many I co-authored, includes men producing and using ethylene oxide in Union Carbide Corporation chemical plants from 1925, the beginning-- the first to ever make ethylene oxide. There's ample evidence of high exposures in the early years of this industry. Publications, spills, upsets in the early years, the men were walking in liquid EO, burns right through their shoes. It's all published.

00:40:25;15

A ten-year update has just been completed of this cohort. It includes follow-up from 1940 to the year 2013. That's 73 years of follow-up of 2,000 men producing and using ethylene oxide in manufacturing. If there were a causal link to cancer at these levels, it would have been identified by now. The study with follow-up through 2003 was available when EPA did their risk assessment, and despite its availability, they didn't use it in their modeling.

00:41:03;04

In addition to reliance on a single study, the EPA risk assessment was derived from, as I had mentioned earlier, the selection of a faulty model for the relationship between ethylene oxide exposure and risk. This is the most influential decision made in the EPA analysis because it modeled the NIOSH sterilin study data using a relationship we call supralinearity, which means assuming risk increases faster in the low-exposure range than in the higher. This is not what one expects with a carcinogen.

00:41:46;14

This resulted in an exaggerated risk estimate at low exposures. Supralinearity. It's contrary to the discussion in the EPA document, itself, which states, and I quote, "It is highly plausible that the dose response relationship over the endogenous range is sublinear, but supralinear." Quite the opposite of the model selected. The supralinear model is also contrary to the expected mechanism of carcinogenicity, to what is seen in the epidemiology studies, including the NIOSH worker communication, which said high exposures, and the mode of action of EO in the human body.

00:42:31;11

Had the EPA used a more traditional exposure response model, which fits the data equally well, the result would have been very different and more plausible. The u-- U.S. EPA's cancer risk assessment guidelines-- they have their own guidelines-- caution that, and I quote here, "A steep slope, that is supralinear, also indicates

that errors in an exposure assessment can lead to large errors in estimating risk."

00:43:02;00

This is relevant to their risk assessment because the NIOSH model, as I mentioned earlier, had some very serious uncertainties in the early years of the industry. The EPA document concludes that lifetime levels-- exposure levels as low as .1 part per trillion-- now unfortunately the previous testimony used nanograms-- per meter cubed and I'm using PPMs and PP-- so there's a translation of those-- those numbers.

00:43:36;23

We won't go into that now, but the EPA level, I think it's easier to understand at part per trillion, .1 part per trillion, they say, poses a cancer risk based on this document that I just described the flaws in. In addition to being contrary to the findings of the epidemiology studies, workers exposed to much higher levels-- this level is so small as to suggest human activities are a health concern (?).

00:44:05;03

For example, the levels of ethylene oxide in ambient air, naturally produced by the human body, and the levels exhaled in human breath are hundreds, if not thousands of times greater than the minute exposure level that EPA calculates as posing a risk to humans. The EPA cancer risk value is an implausible exaggeration and strains scientific credibility.

00:44:30;23

It is therefore scientifically incorrect to draw inferences about cancer risks to populations potentially exposed to ethylene oxide using this EPA cancer risk number, as has occurred in the ATSDR report and the NATA 2014 assessment. Just one final thing I want to say. I-- I've worked with communities over my 40 years-- communities' concerns, and mostly it's cancer. And cancer is-- a tragic disease, and I am very sympathetic because people always want to know, "Why? Why did I get this?"



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00:45:09;20

And for some cancers, we know a great deal, such as lung cancer, we know smoking attr-- con-- counts for over 90%, but there are many other cancers that have risk factors, but very few-- not a great deal that we know all of them why, why. There's a big gap-- for many of these cancers. And-- it's sad and-- and I'm sorry for the pain of this community, but I think there's unwanted-- unwarranted fear that it's ethylene oxide. Thank you.

SEN. DAVID KOEHLER, CHAIR:

00:45:42;09

All right. And you have about two minutes to conclude this-- part of it.

THOMAS TRIMBLE:

00:45:46;22

All right, no, that will work fine. Good morning-- Chairman and members of the committee. My name is Thomas Trimble. I'm with-- the Advanced Medical Technology Association and with the National Association of Medical Device Manufacturers, so coming at this with a little different perspective.

00:45:59;18

But our members are very concerned about this issue and the potential that this legislation could ban ethylene oxide, which they rely on very, very much. So-- (UNINTEL) we have about 400 members in our-- association and about 45 of them have facilities in Illinois. And-- I think roughly about 30 million products are sterilized with-- ethylene oxide in Illinois on an annual basis.

00:46:24;21

And-- I mean the medical products and pretty much anything that's used to diagnose and treat a healthcare condition that's not a drug. So, it's really the wide range of-- bandages and sutures, to-- implantable-- hip replacements, knees, cardiac devices, imaging equipment. So, a very wide range. Obviously all of those don't-- require ethylene oxide, but a lot do. Some that-- because they're-- the way they're manufactured to be biocompatible with the body, have to have certain characteristics.

00:46:56;00

And-- other-- sterilization processes don't accommodate them as well, like some plastics that-- with other processes that may have high temperatures or moisture in them or radiation that causes the-- the products to become brittle when you want a flexible product. So, that's-- prohibitive to use other products-- other processes than EtO. And those other factors as well can-- cause damage to-- mechanical and electronic-- components in devices.

00:47:22;25

So, again, that's why we-- we are not aware of any other suitable alternative for ethylene oxide-- for many, many of these devices. So, just-- a little background that might be helpful for-- medical devices now. The FDA as well-- the federal FDA has a bit of a role in-- this. I mean, FDA approves devices, but they also look very thoroughly at every step of the manufacturing process and even post-manufacturing, when products are with patients, and track-- make sure everything is done to be--

ensure the safety and effectiveness of devices.

00:47:55;07

And-- even the-- they look at the-- sterilization process in terms of-- contracting out because they see that as an-- extension of the manufacturing process. And-- companies are required-- I mean companies that-- follow-- established sterilization methods-- methods such as EtO must comply with voluntary consensus standards-- that are recognized by FDA as well as global authorities that-- companies are-- are (UNINTEL) international and-- have to follow all these rules and regulations, and follow good manufacturing processes as well.

00:48:28;13

So-- any change to-- the type of-- sterilization process, if there was an-- even an alternative available or the location of their sterilization facility, would have to go back to the FDA in-- in terms of the validation of that process, which-- would be a lengthy process, again-- even if there was, but we're not aware of any-- other

alternative right now.

00:48:50;11                    So, if there was any kind of ban or restriction of ethylene oxide, it would have-- a drastic and negative impact on patient access to technologies that they need. So-- so with that, I'll just conclude and be glad to work with the committee on-- trying to address this issue.

SEN. DAVID KOEHLER, CHAIR:

00:49:05;02                    Thank you to the panel. Committee-- Senator Bush? Senator Biss? Senator McGuire?

SEN. MELINDA BUSH:

00:49:12;05                    Thank you for your testimony. I'd like to ask-- Doctor-- is it Tata?

DR. JANE TATA:

00:49:16;24                    Yes.

SEN. MELINDA BUSH:

00:49:17;26                    Sorry. Can you tell me-- so, are you paid by Medline to be here today?

DR. JANE TATA:

00:49:22;27                    I work for Exponent. Exponent will bill Medline and they'll pay Medline and I will bill Exponent

(LAUGH) for my time.

SEN. MELINDA BUSH:

00:49:31;17

Okay. So, is it also then your testimony that the maps-- on the EPA site that show-- both certainly the areas surrounded-- Vanguard and Medline and my communities-- and the map-- Millbrook (SIC)-- sorry, Willowbrook, that those maps are incorrect?

DR. JANE TATA:

00:49:52;03

Yes, it's-- it's incorrect because they're using that EPA risk n-- number.

SEN. MELINDA BUSH:

00:49:59;03

So, that's your opinion?

DR. JANE TATA:

00:50:00;12

That's my opinion, absolutely.

SEN. MELINDA BUSH:

00:50:01;25

Okay. I just wanted to clarify that. I also have a couple of more questions. So, it is your testimony there is not another material, another gas, or another material that could be used to sterilize equipment. Is that what your testimony was? Yes, I'm sorry.

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THOMAS TRIMBLE:

00:50:19;26 That's my understand.

00:50:23;13 (OVERTALK)

SEN. MELINDA BUSH:

00:50:23;28 It's pretty important testimony. If you're telling us there's nothing else that can be used in place of this?

THOMAS TRIMBLE:

00:50:29;05 That's what-- again-- I'm not a scientific expert on the sterilization processes. From what I understand from our members, that is the-- the case for these products. There are-- (UNINTEL) there's other types of sterilization now, gamma sterilization-- steam sterilization. The FDA-- some companies look at novel (?) sterilization methods, but the FDA looks at those very closely and has not approved that-- other-- new types for many of these devices, so that the--

00:50:55;00 (OVERTALK)

SEN. MELINDA BUSH:

00:50:55;04 And you think that by 2022, that it would be possible that something else could be-- could be

approved?

THOMAS TRIMBLE:

00:51:01;04 Well, I mean, I-- I know a lot of times-- and--  
and I don't know-- I'm not saying that's the case  
here, but--

SEN. MELINDA BUSH:

00:51:05;26 Yeah.

THOMAS TRIMBLE:

00:51:06;14 --policymakers will say, "Let-- let's put a date  
out far enough that something will come up. The  
smart people will-- will figure something out."  
And-- I don't know, you know, maybe that's the  
case, but we-- we don't have any evidence right  
now to-- to say that that's the case. There's  
certainly nothing that's-- a suitable alternative  
right now.

SEN. MELINDA BUSH:

00:51:20;24 Okay. And-- just a couple of more questions. So,  
do any of you live by Sterigenics or Medline or  
Vanguard? I just want to know if you live in  
those areas. Would you-- I guess it's an opinion--  
- you wouldn't consider maps, cancer-causing maps



that the EPA has on-- online and obviously stands behind when you consider where you live. You wouldn't consider those things?

DR. JANE TATA:

00:51:52;23 I'll be happy to answer. Consider--

SEN. MELINDA BUSH:

00:51:54;14 I just wonder if any of you would. When you are locating your family-- to live in a neighborhood-- would you consider-- EPA maps that indicate carcinogens-- unsafe levels of carcinogens? Would you consider that when you are determining where you're going to live with your family?

DR. JANE TATA:

00:52:13;15 If they were legitimate maps-- and I felt confident in the science, sure, I'd consider it. And by the way, I spent 50 years in a blue collar town near factories and I could smell the rubber. I don't come from the suburbs.

SEN. MELINDA BUSH:

00:52:34;25 Perhaps that's not a good thing. Anyway-- I appreciate your testimony. There's obviously a lot for us to learn here. Are there acceptable

levels? I mean, my understanding is, and this is very cursory at this point, is that the-- the problem really arises when it is breathed, as I understand. That's the largest risk.

00:52:55;24

So, I'm wondering why there aren't ways that the emissions-- could be-- scrubbed or-- there-- there aren't ways that we can really reduce them-- to a place where they're almost negligible. I'm certainly not looking to shut down manufacturing-- but I really think there are some serious questions that have to be answered here. Thanks.

SEN. DAVID KOEHLER, CHAIR:

00:53:16;28

Senator Biss?

SEN. DANIEL BISS:

00:53:22;13

Thank you, Mr. Chairman. So, Dr. Tata, you said a lot of things and I want to just make sure we're understanding-- what you were-- getting at. As-- as I understood your testimony, you were basically saying, "Hey, look, there's this scientific report that's been released and-- you know, this is complicated stuff. We have to

assemble models, make a series of assumptions.

00:53:54;02

"We might have some guesses about what we're gonna learn from that." Every single study that would be done on this type of question has those features. And it sounded like what you were saying was you disagreed with some choices that the scientists that conducted the study made regarding what models they were utilizing and you were pretty surprised, to the point of disbelieving, about some of the conclusions that you believe they drew. Is that a fair characterization of your testimony?

DR. JANE TATA:

00:54:23;05

With the exception of the EPA work was not a study. They did not collect any new information. They took information from another study and they manipulated it, and I disagreed with how they manipulated it. But my opinion really comes from the work I've conducted. I studied these ethylene oxide workers over a s-- 73-year--

SEN. DANIEL BISS:

00:54:45;18 And-- I'm-- I'm interested in asking about--

DR. JANE TATA:

00:54:48;04 Okay.

SEN. DANIEL BISS:

00:54:49;06 --their work. And-- forgive me, I'm not an expert in the field. I don't know-- I didn't realize the word study is meant to be used only in that context. What's the appropriate word to use for what they did?

DR. JANE TATA:

00:54:58;14 Well, it's a risk assessment. And study--

SEN. DANIEL BISS:

00:54:59;10 Okay, so their assessment--

DR. JANE TATA:

00:55:00;01 --could be used generically, but I-- I'm trying to make it-- yeah.

SEN. DANIEL BISS:

00:55:00;27 Let's just-- let's stick with-- I just don't want-- I don't want to make any-- mistakes here. Do the scientists, government agencies, other workers that were involved in that assessment

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agree with your characterization?

DR. JANE TATA:

00:55:17;17 Other workers? Oh, you mean those--

00:55:20;05 (OVERTALK)

SEN. DANIEL BISS:

00:55:20;24 Like-- like-- so, I guess what I'm saying is  
there's a dispute here.

DR. JANE TATA:

00:55:25;29 Yes.

SEN. DANIEL BISS:

00:55:27;04 Sometimes in science, the dispute might be, "Oh,  
damn, those guys misread the thermometer," so  
they published a number that was incorrect. Now,  
we can all look back and say, "Yikes, that was  
incorrect." Sometimes two sides would disagree  
about methodology.

DR. JANE TATA:

00:55:43;15 Uh-huh (AFFIRM). Okay.

SEN. DANIEL BISS:

00:55:45;17 Where are we here?

DR. JANE TATA:

00:55:46;18 Okay. This is more than opinion. And we sub--

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SEN. DANIEL BISS:

00:55:49;25 Ah-ha.

DR. JANE TATA:

00:55:50;19 --we submitted a very detailed-- request for  
correction to-- under the Information Quality  
Act, where we objected--

SEN. DANIEL BISS:

00:55:59;26 Who's-- who's we in that context?

DR. JANE TATA:

00:56:01;06 We-- well, like I said, I worked on it, but the  
American Chemistry Council submitted it. And--

SEN. DANIEL BISS:

00:56:05;28 Uh-huh (AFFIRM).

DR. JANE TATA:

00:56:06;23 --we identified actual errors in the report,  
factual errors. It wasn't just opinion.

SEN. DANIEL BISS:

00:56:14;18 And has the-- have the-- those who-- published  
the report agreed with your assessment that there  
were some errors?

DR. JANE TATA:

00:56:20;21 We haven't heard back yet.

SEN. DANIEL BISS:

00:56:21;19                    Uh-huh (AFFIRM). Okay. So, we have what appears to be a difference of opinion between two different collections of experts.

DR. JANE TATA:

00:56:33;06                    I guess you'd call it a difference of opinion based-- hopefully based on fact. Not on--

00:56:37;07                    (OVERTALK)

SEN. DANIEL BISS:

00:56:37;19                    Well, but-- but again--

DR. JANE TATA:

00:56:38;14                    It wasn't interpretation. That's my point. This was not-- we looked at a study and you interpreted the findings a little differently than I interpreted the findings. It isn't that. It's-- it's the methodology incorrect and identifying why it's incorrect.

SEN. DANIEL BISS:

00:56:54;14                    So, you, in your capacity as a person-- making filings with the American Chemistry Council and employed by Exponent, have made an assertion about a methodology that others, for example

those who are not on industry payroll, have not at this time agreed with.

DR. JANE TATA:

00:57:14;14

There-- I-- I assume the EPA disagrees-- the ones who did this report, but I think there are other scientists, maybe even within EPA-- they're not comfortable because the end result is implausible. It doesn't fit with reality.

SEN. DANIEL BISS:

00:57:28;06

Okay.

DR. JANE TATA:

00:57:29;04

So-- the-- you know, you won't to say because I-- I was hired by industry. I'm at the end of my career. This isn't-- I didn't even want to get involved 'cause I know this is gonna be a long, drawn out affair. They begged me to get involved because of my history and my knowledge of ethylene oxide. I don't-- it's not about who paid me. Believe me.

SEN. DANIEL BISS:

00:57:52;11

Well-- as you well know, that standard is not one that most of academia agrees with.



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DR. JANE TATA:

00:57:59;14                   What?

SEN. DANIEL BISS:

00:58:00;23                   The standard of, "Hey, don't worry about who's  
paying the researcher."

DR. JANE TATA:

00:58:04;28                   Oh, I think--

SEN. DANIEL BISS:

00:58:05;06                   That's not a standard that worked very well with  
smoking studies. It's not a standard that works  
very well even in economic studies today. That's  
not a good standard for scholarship. Now, let me  
ask you on this question, you work for Exponent?  
Is that-- that's-- you-- they're your full-time  
employer?

DR. JANE TATA:

00:58:20;14                   Yes. I'm-- I'm now an hourly employee.

SEN. DANIEL BISS:

00:58:22;13                   Oh (UNINTEL). What-- what is Exponent?

DR. JANE TATA:

00:58:24;15                   Exponent is a scientific and engineering  
consulting company.

SEN. DANIEL BISS:

00:58:27;18 And who are their clients?

DR. JANE TATA:

00:58:29;10 Everything. Government, industry-- any complex problems. They do accident investigations. Anyone who comes for help with complex problems of-- scientific or engineering.

SEN. DANIEL BISS:

00:58:43;17 Got it. Were they, or you personally, or other groups that you're involved with-- in some contractual basis a part of an effort to persuade the government not to release the risk assessment?

DR. JANE TATA:

00:58:55;12 No, I wasn't.

SEN. DANIEL BISS:

00:58:57;13 Okay. Good to know. Well, thank you. I-- I just think that this is a really, really important distinction that we've just talked about. There is a dispute, different people have different positions. That's healthy. That's how scholarship works.

00:59:15;29                   In this instance, the people of one position are on payroll. That-- I'm not saying you're a bad person. I'm not saying you're a dishonest person. I'm saying you are not neutral and your credibility is therefore not the same as those who advance the other side. Not because of who you are, but because of the way in which centuries now of evidence demonstrate what happens when one side in a scientific dispute is on the payroll of somebody who has a financial interest in the outcome. That's just how these things have worked forever. Thank you very much.

SEN. DAVID KOEHLER, CHAIR:

00:59:54;20                   Senator McGuire?

SEN. DANIEL BISS:

00:59:56;24                   Thank you, Mr. Chair. Dr. Tata, I appreciate your lifelong interest in worker health and safety.

DR. JANE TATA:

01:00:02;12                   Thank you.

SEN. DANIEL BISS:

01:00:03;13                   And following the questioning of-- he's not

Senator Solokof (PH) or Senator Sam Epstein (PH).  
He's Senator Daniel Biss, (LAUGH) right. I think  
we know-- or knew some of the same people. So,  
who classifies-- ethylene oxide as a carcinogen?

DR. JANE TATA:

01:00:23;20

That's a good question. It's done by numerous  
health agencies, okay. And they all have their  
criteria for classification. So, one of the most  
important is the International Agency for  
Research on Cancer, IARC, in Europe-- France. And  
then there's the National Toxicology Program and  
then there's the U.S. EPA.

01:00:48;24

And they do these-- these independently and they  
classify. At one time, the criteria of all  
agencies was sufficient human data to classify as  
a known h-- human carcinogen. About ten years  
ago, IARC changed their criteria because everyone  
agrees with ethylene oxide. EPA, me, all the  
scientists agree that the human data is not  
sufficient. The 13 studies is not sufficient to  
class-- to say ethylene oxide is a carcinogen.

It's all agreed. It's in the document.

01:01:25;07

I didn't give that quote, but it's in the document. But they said, "What we're going to do is even if the human data's limited, we're going to look at animal data, we're gonna look at mechanistic data. And if we think there's corroborative support from those other avenues, we're s-- we're gonna raise it to the level of known human carcinogen."

01:01:45;26

And that is what happened at IARC. And I was an invited participant there. The epidemiologists came out and said it's not sufficient. And the others said, well, animal and all this, and it got raised. EPA just, in this document, also took on that same criteria and called it human. They say right in the document it's not sufficient, human.

SEN. DANIEL BISS:

01:02:08;17

Is ethylene oxide classified as a carcinogen by the U.S. EPA?

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DR. JANE TATA:

01:02:12;10 It is.

SEN. DANIEL BISS:

01:02:13;24 Is ethylene oxide classified as a carcinogen by the Federal Occupational Safety and Health Administration?

DR. JANE TATA:

01:02:21;17 OSHA?

SEN. DANIEL BISS:

01:02:21;27 Yes.

DR. JANE TATA:

01:02:23;01 I haven't seen the la-- OSHA hasn't had anything in a very long time, so I haven't look at OSHA's--

SEN. DANIEL BISS:

01:02:28;16 Is ethylene oxide--

DR. JANE TATA:

01:02:29;07 --classification.

SEN. DANIEL BISS:

01:02:29;18 --classified as a carcinogen by NIOSH?

DR. JANE TATA:

01:02:33;14 I haven't looked at their document lately either.

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Probably, but-- I haven't looked at it.

SEN. DANIEL BISS:

01:02:37;11

But, Doctor, you--

DR. JANE TATA:

01:02:38;14

I don't know that they have-- I don't know that NIOSH does the same thing. They're the arm of OSHA. They're the research arm of OSHA. So--

SEN. DANIEL BISS:

01:02:44;25

Well, of CDC, right. But-- but Doctor, you've disputed NIOSH's methodology, if I understood your-- your testimony. You've disputed NIOSH's methodology in recommending a lower exposure limit, yet you don't know if NIOSH classifies ethylene oxide as a carcinogen?

DR. JANE TATA:

01:03:06;16

I was talking about the NIOSH conducted research of EO, the sterilin plant worker study, not how they classified. That study was an independent published epidemiology study that was used by EPA. And I criticized how EPA used that study.

SEN. DANIEL BISS:

01:03:25;19

Okay. So, the-- the-- federal EPA classifies

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ethylene oxide as a car-- carcinogen.

DR. JANE TATA:

01:03:31;03 Excuse me? Who did? The EPA did?

SEN. DANIEL BISS:

01:03:33;23 EPA did.

DR. JANE TATA:

01:03:34;02 Yes, they classified it.

SEN. DANIEL BISS:

01:03:34;19 Okay. And you mentioned that in the '20s, at a Union Carbide plant, that workers were wallowing in ethylene oxide.

DR. JANE TATA:

01:03:39;13 Well, in the early years of the industry, yes.

SEN. DANIEL BISS:

01:03:41;08 Pardon me?

DR. JANE TATA:

01:03:41;19 By nine-- in the early years--

SEN. DANIEL BISS:

01:03:43;02 Okay, right.

DR. JANE TATA:

01:03:43;16 --of the industry.



SEN. DANIEL BISS:

01:03:44;16 Right. Okay. Has the worker exposure limit been lowered over time?

DR. JANE TATA:

01:03:50;23 Certainly. Around 1978 and with c-- OSHA, the levels dropped.

SEN. DANIEL BISS:

01:03:55;08 Okay. Okay. And what has the rationale been for lower-- for setting an exposure limit to ethylene oxide and then reducing it?

DR. JANE TATA:

01:04:02;27 Why did OSHA do it? Oh, the-- I would say, in the '70s-- in 1979, Union Carbide conducted-- a rat study and it showed that at 100 parts per million, the rats had an increased risk of cancer. And that started, you know, the concern and everybody dropped. OSHA came on and, you know, and took it on from there. And then the epi studies began-- epidemiology studies began to be conducted around 1979.

SEN. DANIEL BISS:

01:04:29;23 Okay. And-- so there is a credible animal study--

proving that ethylene oxide causes cancer?

DR. JANE TATA:

01:04:43;04 It is an animal carcinogen.

SEN. DANIEL BISS:

01:04:44;09 Okay.

DR. JANE TATA:

01:04:44;21 And I'm not here saying it definitely is not a carcinogen. I'm saying the evidence is limited. It's not a known human carcinogen, in my view. But I can't rule out-- you cannot prove a negative. I'm saying the limited-- the evidence is limited. It's not a potent carcinogen; I'm absolutely certain of that because I'd be seeing a lot more in these workers.

SEN. DANIEL BISS:

01:05:08;21 And could you give us-- examples of potent carcinogens?

DR. JANE TATA:

01:05:14;18 Vinyl chloride, liver.

SEN. DANIEL BISS:

01:05:17;23 Okay.

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DR. JANE TATA:

01:05:19;14 Benzene (UNINTEL) leukemia.

SEN. DANIEL BISS:

01:05:21;26 All right. Okay. And if I understood you correctly, Doctor, you-- stated that-- well, tell me, you mentioned one part per trillion-- per trillion.

DR. JANE TATA:

01:05:33;20 Point-one. Point-one.

SEN. DANIEL BISS:

01:05:34;29 Point-one, okay, 1/10 of one, okay. Did I hear you say that, as I speak to you, I could be emitting .1 part per trillion of ethylene oxide?

DR. JANE TATA:

01:05:46;18 You're emitting hundreds of times more than that, .05 to one part per billion comes out of mouths. Our body-- inside our body is 1.8 part per billion, thousands times higher than the EPA risk number.

SEN. DANIEL BISS:

01:06:01;16 Okay. And-- and tell us the relevance of that to workplace exposure and community exposure.

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DR. JANE TATA:

01:06:08;25 Well, what I'm saying is the level at which EPA-- declares there's a risk to-- humans is many times lower than what is all around us, what we produce in our body. And it's un-- it doesn't pass the reality check. And-- and when you do m-- monitoring, this measurement is so complicated around communities because you're getting EO from cars, you're getting EO from smokers, and you're getting EO from the ambient air. And then you-- you're trying to say, well, how much of that is coming from the plant? That's why they do modeling instead of monitoring many times. The ATSDR did-- put canisters around.

SEN. DANIEL BISS:

01:06:56;08 And what is ATSDR, Doctor?

DR. JANE TATA:

01:06:57;17 That's the one that did the report--

01:06:59;19 (OVERTALK)

SEN. DANIEL BISS:

01:06:59;29 Okay. And-- and-- and about the different sources of human exposure to ethylene oxide, okay, maybe

my Buick Verano emits some, maybe my corpus emits some, but-- the source concentration would not equal that of a manufacturing plant or a sterilizer.

DR. JANE TATA:

01:07:27;07 You're absolutely right.

SEN. DANIEL BISS:

01:07:28;12 Right? Worker exposure is eight hours a day, 40 hours a week, additional exposure if there's any overtime work.

DR. JANE TATA:

01:07:34;24 And that's why--

SEN. DANIEL BISS:

01:07:35;03 There are time-weighted averages, the average exposure--

DR. JANE TATA:

01:07:37;19 Uh-huh (AFFIRM).

SEN. DANIEL BISS:

01:07:39;09 --over a work day. There are peak concentrations.

DR. JANE TATA:

01:07:41;26 Absolutely. And that's why you have to do studies of those workers to see--

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SEN. DANIEL BISS:

01:07:44;01 Right, which could exist in a community which surrounds a facility which is having egregious emissions of ethylene oxide.

DR. JANE TATA:

01:07:51;22 Well, I-- I'm not aware-- I'm not knowledgeable about the emissions from the plant, myself. That's not what I'm here to talk about. I could just tell you what our worker study shows, with high exposures, and then you have to have lower exposures to the community because they're a more vulnerable population. And it's my understanding, and someone else would have to prove it, that their levels are lower than the workplace.

SEN. DANIEL BISS:

01:08:18;24 Wait, say that again. Someone would have to prove that--

DR. JANE TATA:

01:08:20;20 Well, someone-- you know--

SEN. DANIEL BISS:

01:08:21;27 That the kid waiting for the school bus, that his exposure is--

DR. JANE TATA:

01:08:26;07 Less than what--

SEN. DANIEL BISS:

01:08:26;15 --less than-- than his mother who works in the  
plant?

DR. JANE TATA:

01:08:29;27 One PPM is considered reasonable for workers.  
Whatever the community's exposed to must be,  
should be lower than that, but we have trouble  
monitoring, but I have to think that what comes  
out of the stack, if it's only 1% emission, that  
the community would have a much lower, by the  
time it gets out and gets dispersed to the  
nearest neighbor, it's less than what workers  
get. And the studies suggest workers are not  
getting high rates of cancer from high levels of--  
- of EO over many years.

SEN. DANIEL BISS:

01:09:08;04 Of course, perhaps the reason a study might not  
show excess incidence among workers is because  
that plant is controlling worker exposure to this  
carcinogen.

DR. JANE TATA:

01:09:19;08 Not in 1940, '50, '60. That's when the majority of the exposure in these workers started. I started collecting the workers in 1940. We stopped even looking after '78, including NIOSH. They said, "Look, the lower-- the levels are so low after '79-- or '78, don't even bother adding new workers onto the cohort." So, our studies cover a heavy exposure period.

SEN. DANIEL BISS:

01:09:46;10 One final question-- I think one final. So-- a previous witness-- stated that NIOSH's recommended exposure limit is 100-- 180 nanograms per cubic meter. Do you know when that recommendation was made?

DR. JANE TATA:

01:10:05;12 I think it's old, but I don't know.

SEN. DANIEL BISS:

01:10:07;07 Do you know-- but in what decade? You-- you-- I think I just heard you say that studies of worker-- mortality due to exposure to ethylene oxide ended in 1978? Did you say that?



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DR. JANE TATA:

01:10:20;21                   Began. Began. The-- the studies appeared in the literature starting in '79.

SEN. DANIEL BISS:

01:10:26;13                   Okay.

DR. JANE TATA:

01:10:27;15                   But some of them, like ours, went back in time, retrospectively--

SEN. DANIEL BISS:

01:10:30;14                   Right.

DR. JANE TATA:

01:10:31;02                   --to study workers, yes.

SEN. DANIEL BISS:

01:10:31;21                   Okay. All right. But it-- it appears that there was continued scientific assessment of-- the risk to human life posed by ethylene oxide.

DR. JANE TATA:

01:10:42;07                   I'd have to--

SEN. DANIEL BISS:

01:10:42;16                   That the-- that the-- that the-- that the jury-- the scientific jury has not returned its verdict.

DR. JANE TATA:

01:10:49;01           My opinion, there will not be-- anymore. Our study s-- is 73 years of follow-up. I'm not gonna study them anymore. They're all-- 70% of them have died by now. They're old.

SEN. DANIEL BISS:

01:11:02;03           Right.

DR. JANE TATA:

01:11:03;14           NIOSH-- I don't think-- they can't even find the data that they used for part of this, so I don't see them updating their study. So, where is it gonna come from?

SEN. DANIEL BISS:

01:11:15;09           But--

DR. JANE TATA:

01:11:16;07           I don't think you'll see any more.

SEN. DANIEL BISS:

01:11:16;24           Respectfully, if I understand you, you're talking about one cohort that worked for one corporation early in the 20th century. We're talking about current exposure, current day-to-day exposure--

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DR. JANE TATA:

01:11:31;06 Uh-huh (AFFIRM).

SEN. DANIEL BISS:

01:11:32;17 --to workers and community residents. And it appears, based on what we've heard today from both panels, that-- scientific assessment of the risk posed by ethylene oxide continues, that a definitive answer has not been reached, that the case is still open. Thank you.

SEN. DAVID KOEHLER, CHAIR:

01:11:56;01 Senator Morrison, and then we'll follow-up question from Senator Bush.

SEN. JULIE MORRISON:

01:12:01;10 Thank you, Mr. Chairman. I represent-- a significant part of Lake County as well, and this is obviously on my radar. Today I have just two quick questions. The first-- in terms of the sterilization process, I thought I heard from other-- other people providing testimony that St. Anthony's and Swedish Covenant no longer use this-- the same process that is in question, that there is a different sterilization method. So, am

I-- can you-- can you help me re-- justify what your response was on that in terms of medical equipment? Yes, you. Sorry.

THOMAS TRIMBLE:

01:12:41;07

That's all right. I-- well, I-- I think I'd have to, if I could, look into that and get back to you because I really can't speak to what the hospitals are doing on it. Yeah, I-- I-- I think they're-- they may-- it may be that there are different devices that-- some-- some of the ones I mentioned are-- are one-time use and some of those surgical kits come through, the kits will have everything together for all different types of surgery. There's an example here I think, that all are packaged together, that's sterilized with ethylene oxide. And-- so, again, after the surgery, that-- that's not gonna be reused. So--

SEN. JULIE MORRISON:

01:13:12;15

But there are other FDA-approved methods that are-- it sounds like are being used in Illinois.

THOMAS TRIMBLE:

01:13:18;03

In-- in the hospitals?

SEN. JULIE MORRISON:

01:13:19;27 Uh-huh (AFFIRM).

THOMAS TRIMBLE:

01:13:21;14 Again, I can't speak to what the hospitals are doing. I could-- I could see if I can find more data to-- or information about why there's a difference between hospital and manufacturing-- and the manufacturing products, but I-- I don't--

SEN. JULIE MORRISON:

01:13:34;04 My second-- my last question is obvi-- (NOISE) obviously this happens all over-- I'm so sorry. Just like home. My other question-- revolve-- I always ask about other states. What other states have come forward with similar problems, similar questions, similar occurrences of disease and-- and confronted-- and confronted you guys with the same concerns?

THOMAS TRIMBLE:

01:14:10;09 So, I-- I can't address that. I've heard some anecdotal information. I think the-- EPA director may be able to talk a little bit about-- some other states have been doing on this, but-- I-- I

don't--

01:14:18;22

(OVERTALK)

SEN. JULIE MORRISON:

01:14:19;09

But he's-- he's only Illinois. I'm asking what other states-- this seems especially a doctor who is, you know-- nationally known person who's, you know, has some expertise in this with a long career. I'm wondering if any other states have-- that you've had to-- come in and do similar testimony.

DR. JANE TATA:

01:14:44;29

I have routinely-- I worked for Union Carbide for 18 years and I routinely went to speak to communities around chemical plants and show them the epidemiology studies that we were doing. They didn't raise a particular concern, but I would routinely tell them, "We've done this study and here are the results." They were interested in their cancer rates. Living around chemical plants, they were.

SEN. JULIE MORRISON:

01:15:11;17

With this particular ethylox (SIC)--

DR. JANE TATA:

01:15:15;19 Ethylene oxide.

SEN. JULIE MORRISON:

01:15:16;02 Yes. With this particular element?

DR. JANE TATA:

01:15:19;27 I don't recall, other than there was an explosion at one of the chemical plants years ago. And then-- there were concerns, well, there weren't short-term effects, what about long-term effects? And I do believe I went down and spoke to the community about that.

SEN. JULIE MORRISON:

01:15:39;14 Okay. Okay, thank you very much. Senator Curran, I'm gonna be signing on as a sponsor today with your permission.

SEN. DAVID KOEHLER, CHAIR:

01:15:48;18 Senator Bush?

SEN. MELINDA BUSH:

01:15:52;15 Just a follow-up question. My understanding is that Sterigenics-- installed something called backventing. Is that something that we are seeing required in other states-- because my

understanding is that is something that's being looked at in other states and is being required-- for plants that are using ethylene oxide.

BRAD BABCOOK:

01:16:15;08

Senator, from what I know-- and this would probably be a better question for Director Messina. They're the ones that approved-- the construction permits for that. So from-- but my understanding is, yeah, that is-- that is correct. There's been-- other type controls-- being put on that which has actually reduced it. And from what I know, I think it's a scrubber of-- some sort (UNINTEL).

SEN. MELINDA BUSH:

01:16:35;17

Thank you.

SEN. DAVID KOEHLER, CHAIR:

01:16:38;23

Yes, any other questions from the committee? We took a little longer time there, but I thought it was important to get the-- questions answered-- from the committee. So, thank you, panel. Director Messina? And I just talked to Mark. I think one of the questions that we should-- do



some research on is what other states are doing to address this issue. That's a good question. Director, thank you.

ALEC MESSINA (IEPA):

01:17:03;14

Thank you. I appreciate it, Chairman, and members of the committee. Happy to answer any questions that you have-- and there were a number that were raised-- during the previous panels that I'd like to maybe expand on a little bit. I think, you know, Senator Bush, you said something that-- that I repeat over and over again-- thank you, sorry.

01:17:23;03

There-- there is a lot that we are still learning. And-- and this has been a challenge for-- for really-- not just U.S. EPA-- Illinois EPA, we're all kind of grappling with a lot of these issues. I am happy to talk about what other states are doing as well. But anyway, with that, I-- I-- you know, I-- I know I've-- I'll try and stay true to the ten-minute panel commitment that you had--

SEN. DAVID KOEHLER, CHAIR:

01:17:45;27                   That we've already violated.

ALEC MESSINA (IEPA):

01:17:47;17                   Yeah, I'll-- I'll do my best to stick with that.  
First of all, you know, I-- I want to be clear--  
because I do-- I do get a lot of emails and phone  
calls from folks-- in the s-- in the Willowbrook  
area and-- and the surrounding communities. And I  
want to make it clear that, you know, we-- we  
understand how critically important this issue is  
and we have every intention of working with--  
Senator Curran and the other House sponsors and  
other stakeholders to come up with something  
that-- that does have a positive impact and can  
be implemented.

01:18:16;16                   We do have some concerns with the language that's  
out there from an implementation aspect. But--  
certainly we want to work-- cooperatively and  
collaboratively to get something that-- that we  
can implement. With that-- I'll-- I'll really  
just-- maybe provide a brief update on kind of

where we are at with a couple of different things that have gotten some attention and then-- and then really just-- raise some-- some general thoughts that we have about the-- the language that's out there now and then certainly answer any questions that you have.

01:18:47;11

So, first of all-- I-- many of you may know, but on the off chance that you-- that you haven't yet heard-- you know, we-- we have referred a matter over to the Illinois attorney general's office relative to Sterigenics. We've been working with them, hand in hand with the attorney general's office, that is hand in hand-- both before that referral went over on October 1st or 2nd-- and-- and certainly have been-- meeting with them regularly, not just to take a look at this single facility, but at other facilities as well.

01:19:15;01

Ad I think that was another one of the questions that you asked of the last panel, so I can expand on that. Item two-- so Sterigenics did install

venting. We issued a permit in June of this year that authorized the-- installation and construction of vents-- venting from their back vents, which were at the time uncontrolled.

01:19:42;23

And that venting would then route to the stack where a scrubber exists. So-- the-- as a part of that construction permit that we issued in June, and I believe that became fully operational on July 27th of this year-- the construction permit also required stack testing to occur. That occurred to September 20th and 21st.

01:20:06;10

We received an initial report from-- the vendor-- that-- that conducted the stack test. We were actually present during the test. U.S. EPA was present, and a representative of the village of Willowbrook was present. We raised some issues with the initial report. They've updated that. And we intend to post the revised report on our website. If it didn't happen yesterday, it should happen today. But the-- we have completed our

review of that report and should be able to speak knowledgeably about that very shortly.

01:20:37;03

But-- certainly the initial indications are very positive in terms of an emission reduction impact. And then finally, the third point I will note-- is, I think Senator Curran noted, that we announced last week-- a joint effort with the DuPage County Department of Public Health to test private wells in the-- in the surrounding area-- surrounding-- in the area surrounding the Sterigenics facility.

01:21:03;21

The county health department is engaged in a canvassing effort that I believe began on Tuesday. They intend to use-- a website, various forms of electronic communication and following that up with door to door-- door-knocking-- for two purposes. One is to really ground truth the maps that we have currently to-- to ensure that we know where all of the private wells are that are used for drinking purposes, as opposed to

irrigation. That's our primary focus obviously.

01:21:33;03

And then once we ground truth those maps, to obtain access agreements so that our agency staff-- can then-- enter onto the properties, take the samples. We've-- contracted out with a-- private-- third-party laboratory to analyze those samples. And then it's actually the Illinois Department of Public Health that provides notice certainly to the homeowners first, and then we will-- once we make those notifications to homeowners, we'll be able to speak generally about what-- what those results showed.

01:22:04;05

And then, of course, potentially at least, depending upon what those results show, we will expand-- we're-- we're focusing on-- at minimum, the half-mile radius with-- surrounding Sterigenics. We believe that we'll be able to do at least a mile. And then, again, depending upon what those initial results show, we'll be able to expand-- from there.

01:22:24;12

So-- again, I-- just-- a couple of things I wanted to focus on with regards to any future legislative efforts, things that are in our-- the agency's mind as we move forward. And I'll just focus on three. So, first-- the various proposal have-- have suggested, or would require Illinois EPA to promulgate or propose rules that would create a s-- a-- what I'll refer to as a unique emissions standard for either ethylene oxide or sterilizing facilities that utilize ethylene oxide.

01:22:58;14

And-- and I just-- a couple of things. One, Illinois-- and specifically the agency, has never adopted an-- our-- our own emissions standard for a hazardous air pollutant. What we do do is we really on U.S. EPA, that adopts these NESHAPs, and we incorporate them by reference. Now I'm gonna-- a quick tangent here because I know, Senator Bush, you-- you reference-- and I think also Senator Morrison, you asked questions about

what other states are doing, and I do want to talk about that really quickly before I hit these other two items.

01:23:32;26

The majority of states that we-- we see have-- have done as Illinois has done, and that is adopt-- incorporate by reference that NESHAP. Minnesota, Texas, Michigan, North Dakota, South Dakota-- Indiana incorporate-- by reference that NESHAP. Now, there are a handful of states that use that as a starting point and then move beyond. And I think that's kind of-- that's what we're really-- I think that's what-- one of the things that we want to do on a case-by-case basis.

01:23:59;04

And what I-- what I mean by moving beyond is the NESHAP does not require control of those back vent or exhaust emissions. And so, I-- and so-- let's see, North Carolina, Washington, California-- (MAKES NOISE) I'm sorry, my notes aren't the most organized. I think there are a



couple of other states as well that-- that take that approach.

01:24:23;15

So, they're not setting a unique emissions standard. It's-- it-- but think of it as a, you know, for those of you are familiar with the work that we do, kind of a best available control technology approach. And so, that's-- that's-- certainly I-- you know, I think that would be-- would have been required of Sterigenics if we go down this path where we're requiring something different than just that NESHAP, where they're controlling those back vents.

01:24:48;17

We are in-- (CLEARS THROAT) excuse me. We've had conversations with other facilities-- in the-- in the area as well, those facilities that have been identified by that-- by that national air toxics assessment. And-- and we're looking at similar approaches with those facilities as well. And I would expect them to be coming in surely (?) to-- to the extent that they can get ahead of the

scrutiny that they're seeing elsewhere.

01:25:17;11

States, including Illinois, do not have the resources or experience to develop and promulgate emissions standards for (UNINTEL). That's why we rely on U.S. EPA. Such resources include the ability to analyze and make risk assessments. Further regulations that would address sterilization techniques are not found in state law, but are regulated by the FDA. And-- there's also been some discussion about OSHA as well.

01:25:38;09

And I would just be loath to put the Illinois EPA-- who does not-- who-- who, by and large, do not have those same-- that same level of technical-- those technical resources, I would be loath to put the Illinois EPA in the shoes of the FDA or OSHA, who have experience and expertise in these areas. Item two, there's been some discussion about alternatives, and I'll expand on that in a moment, but I just would first note that-- the various proposals would-- would

require Illinois EPA to make decisions on subject matter that is outside of-- of-- of our expect-- expertise.

01:26:16;04

There's a discussion of whether there are substitute steri-- sterilization technologies available. There have been discussions about-- worker safety. Certainly the-- after the first Willowbrook forum-- that attended, and other U.S. EPA, ATSDR-- the very first phone call I made was to the Illinois Hospital Association and said, "Listen, this is something-- these alternatives are going to be critically important. We're gonna have to answer these questions and we need your help to be able to answer those questions."

01:26:45;23

So, we have had conversations about-- gamma radiation, steam, hydrogen peroxide. I'm not an expert in this area-- but I will tell you anecdotally (LAUGH) what I've heard is that-- ethylene oxide is-- is the-- is the sterilizer of choice because gamma radiation-- has too harsh of

an effect and-- and oftentimes can destroy the-- well, destroy is probably a strong word, but-- but destroy that material that they're-- that they're sterilizing.

01:27:17;16

Hydrogen peroxide does not have the same penetration. There's also been a discussion about hospitals-- getting out of the business of using ethylene oxide-- as a sterilizing agent. And-- and I think that there have been some discussions. And we've been working with the Hospital Association and reaching out to hospitals that currently are permitted to use ethylene oxide.

01:27:37;26

And what we have been told-- and again, this anecdotal information, but it-- it kind of points to the fact that there's so much work that needs to be done as expeditiously-- expeditiously as possible. And that is many hospitals are contemplating no longer using ethylene oxide, but the vast majority of medical equipment that they

have comes from commercial sterilizers that are using ethylene oxide.

01:28:01;28

So-- there are alternatives. Are all of those alternatives available and acceptable for use on all equipment? I don't know. But certainly the FDA is-- is telling manufacturers that that's what-- that's what they must use. So, and you know, I-- I think that there's a lot of work to be done in this area of alternatives, but-- that's-- that's, again, that's not something that the agency is capable of.

01:28:25;16

I said I was gonna be less than ten minutes, and I'm not. So-- (LAUGH) the last point I'll just note, and-- and that is-- you know, there is-- I-- I do have a concern that-- that we-- as we move forward in this-- important area, that we ensure that there is at least some semblance of due process.

01:28:42;07

Various proposals have talked about permit

revocation-- and-- and I don't believe it's Senator Curran's, but as we're talking about all these different things and different approaches-- one-- one piece of legislation that I reviewed-- referenced that-- and the quote is, "The revoking of permits that the agency believes are significantly endangering the public health are not subject to existing Pollution Control Board review procedures." And I just think that's something we need to be mindful of as we move forward. So, those are the-- the three items that I wanted to address and I'm happy to try and answer any questions you have.

SEN. DAVID KOEHLER, CHAIR:

01:29:11;25

Yeah, I-- I-- I have a question-- and then we'll open it up to the committee. So, basically the panelists that-- represented the industry-- I heard two things there. One was about-- that there were no alternatives available. And I didn't know whether that was-- in terms of the-- practical, you know, matter of sterilizing or whether it was just a preference that-- that--

that-- people didn't-- didn't prefer to use anything else.

01:29:41;29

So-- you've-- you've-- addressed that a little bit, but I think that-- the committee-- if I can speak on behalf of the committee, would like to-- be kept abreast of all-- any-- any discussions and any-- insights that come about-- whether there are viable alternatives-- that exist-- an-- anywhere in this nation-- because I think that's an important factor.

01:30:02;28

The-- the other part of the testimony that-- that-- kind of confounds me-- is that-- the U.S. EPA numbers are just not believed. Now, as citizens, we kind of depend upon our government agencies to give us good information, which we expect to be objective and to be accurate. So, what are we supposed to believe?

ALEC MESSINA (IEPA):

01:30:33;05

That's a phenomenal question and it's one that-- Mayor Trilla and Senator Curran and Leader

Durkin, and myself, and countless other people have grappled with because-- I-- I don't think that-- the information that was made available publicly was really presented with sufficient context.

01:30:53;21

It's certainly been clear, and I-- you know, I-- I'm-- I-- I think there's a lot more work that needs to be done, but I think that there were certain assumptions that were made in some of these-- studies. You know, we-- there was a discussion yesterday about the ambient air monitoring that U.S. EPA conducted in May of this year.

01:31:11;03

And there were-- there were some data points that were excluded because they were attempting to come up with the most conservative way of looking at this as possible to determine if they were even gonna do further research and review. And that context was-- was missing as they conveyed that information to the public-- not just the



public, but to the Illinois EPA and the-- the Illinois Department of Public Health, and so forth.

01:31:33;15

So, it has been frustrating. Senator Biss noted, and I-- I-- (LAUGH) I-- I was nodding as you were asking questions because-- you know, there-- there is some question as to e-- even whether there is complete agreement within U.S. EPA, frankly, as-- as-- what those studies show, whether the studies were designed in such a fashion to have something that was valuable and worthwhile and could be conveyed.

01:32:07;09

And-- and-- and my frustration is, you know, being-- you know, we rely on them, too. We rely on them to-- to-- develop a NESHAP that is protective of human health and the environment and-- and-- and as do all other states as well. And so, you know, when there is that uncertainty, we ask them to do their best to eliminate that uncertainty and speak with one voice. And I think

that's been apparent over the last several months as they frankly have walked away from some-- that certainly have walked away from the ambient air monitoring that they did, and-- and other things.

01:32:40;09

And so, you know, we've-- a lot of elected officials have-- have urged them to-- to do these follow-up studies so there can be a-- a comparison after that control equipment was installed, with-- with what we know to be the case beforehand. So, it's-- it's-- it's a challenge. Everyone is fearful and frustrated. And I-- and I appreciate that. And it's-- it's been very difficult for all of us to try and speak knowledgeably as-- about their position.

SEN. DAVID KOEHLER, CHAIR:

01:33:08;16

Well, I-- I guess-- here's what my expectation is, and-- and-- I know we're gonna be-- in an administrative change here-- come January. But-- I think that-- for us who deal with Illinois legislation, that we have to hear truth from the EPA as to-- you know, I don't expect you to have

experts in all the areas and to try to duplicate  
OSHA or-- or-- U.S. EPA.

01:33:35;13

But I do expect that we have an interpretation to  
say, yes, this-- we confirm this or no, we think  
there's some-- some false here, because we have  
to have accurate information if we're to make a--  
a-- reasonable decision on this. I-- I think it--  
it-- it behooves us that we-- as legislators,  
have been confronted with a crisis situation. We  
have to take some action. And-- and what we need  
to work on is to make sure we take the right  
action.

ALEC MESSINA (IEPA):

01:34:04;17

Absolutely. And I couldn't agree more.

SEN. DAVID KOEHLER, CHAIR:

01:34:07;19

Senator Bush?

SEN. MELINDA BUSH:

01:34:10;25

Thank you, Director Messina. I have a couple of  
questions. Do we know of other manufacturing--  
that uses EO, where we might be dealing with  
emissions, in addition to sterilization?

ALEC MESSINA (IEPA):

01:34:22;10                    Yes, we do. There are-- four or five-- facilities throughout the state of Illinois that use it in-- in various capacities.

SEN. MELINDA BUSH:

01:34:31;04                    Okay. And you said something that really piqued my interest for Lake County-- that you are looking at wells-- in DuPage at this point. Where these plants are located, and frankly I'll be going to visit them so I have a better understanding of what's going on and how the processes work, they are located next to communities that are all on private well. Wadsworth abuts Gurnee and is very close to, I believe, the Vanguard plant. So, are we working with the Lake County Health Department?

SEN. DAVID KOEHLER, CHAIR:

01:35:05;12                    Can-- can-- can we just pause for one second, go into a regular meeting, and-- adopt your-- Senator Bush, your-- motion? Because we're losing our quorum.

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SEN. MELINDA BUSH:

01:35:15;23 I understand.

SEN. DAVID KOEHLER, CHAIR:

01:35:16;13 Okay. Can we do that?

SEN. MELINDA BUSH:

01:35:17;13 Absolutely.

SEN. DAVID KOEHLER, CHAIR:

01:35:18;02 All right-- so make a motion-- motion-- Senator Biss makes a motion, Senator McGuire seconds it (UNINTEL) roll call.

01:35:26;07 (OFF-MIC CONVERSATION)

SEN. DAVID KOEHLER, CHAIR:

01:35:29;24 All right. So, it's adopted. We'll report it to the-- Senate. So--

SEN. MELINDA BUSH:

01:35:36;07 Thank you.

SEN. DAVID KOEHLER, CHAIR:

01:35:36;21 --go back to your question. Thank you, Senator.

SEN. MELINDA BUSH:

01:35:38;11 You know, I really appreciate all the questions, thank you. So, my question is are we-- in touch with-- the Lake County Health Department--

because obviously we have some concerns about those communities now.

ALEC MESSINA (IEPA):

01:35:51;12

So, at this point, U.S. EPA has taken the lead in communicating with those-- county-- county officials. We've-- obviously I've taken a number of phone calls, spoken with a number of officials in those areas as well. But specifically to your question of the private well testing, you know, I-- s-- we certainly believe that the well sampling that we are about to engage in will confirm what we think will be the case, and that is that we will not find either ethylene glycol or ethylene oxide in any-- I want to use-- choose my words carefully here, in any measurable amounts.

01:36:29;20

In fact, I was just communicating with-- one of the-- one of the local groups in the Willowbrook area working with-- two scientists from Abbot. And we were exchanging emails about what our expectations are-- the-- and-- and what we

anticipate finding. I-- I don't think we're going to see something, but we're looking at this as a high priority-- but also kind of a test case for what we would expect to see elsewhere.

SEN. MELINDA BUSH:

01:36:55;02           Okay. And-- can I ask you-- you probably-- you may or may not know the answer to this. Do you know if either Vanguard (SIC) or Medline have-- the-- the back venting?

ALEC MESSINA (IEPA):

01:37:05;03           Vantage, yeah.

SEN. MELINDA BUSH:

01:37:06;26           Vantage, excuse me.

ALEC MESSINA (IEPA):

01:37:07;20           Right. No-- no-- so, the-- we've had-- we've sat down with both of them. I b-- I would expect developments in both of those cases quickly, but not-- but-- but not with-- not yet.

SEN. MELINDA BUSH:

01:37:21;12           Okay. And then just one more question. You slipped against the bill. Can you tell us why, Director Messina?

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ALEC MESSINA (IEPA):

01:37:27;05 Absolutely. Thank you for-- yeah, I tried to address that in my first-- few s-- sentences, I guess. But-- you know, we do have implementation concerns with-- with the language as drafted, but we are 100%-- I, personally, the agency is completely committed, absolutely, unequivocally committed to working with the sponsors to come up with something that is implementable.

SEN. MELINDA BUSH:

01:37:48;28 Okay. And what are the-- are the-- what are the concerns? The implementable concerns specifically?

ALEC MESSINA (IEPA):

01:37:54;22 Right. So, those were the three that I tried to address--

SEN. MELINDA BUSH:

01:37:57;01 Okay.

ALEC MESSINA (IEPA):

01:37:57;07 --but the first one was just-- number one, the agency does not promulgate rules.



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SEN. MELINDA BUSH:

01:38:01;16                    Okay. Got it.

ALEC MESSINA (IEPA):

01:38:01;24                    It's the Pollution Control Board. But even beyond that, it's just-- do we have the technical expertise, or does any state, for that matter, have the technical expertise to develop an emissions standard. As I said, we think that in terms of control technology, but not an emissions standard. So, that was-- that was item one. Item two was this issue of us making determinations as to-- whether there are sufficient alternative sterilizing technologies. That's really an-- you know, that's FDA expertise.

SEN. MELINDA BUSH:

01:38:28;18                    Okay.

ALEC MESSINA (IEPA):

01:38:28;26                    Certainly we could report back and-- and monitor, but again, making those determinations is probably outside of our purview. And then the third piece was just ensuring that there is sufficient due process, so if the agency were to

take that action to revoke a permit, that you know, there was some due process surrounding that.

SEN. MELINDA BUSH:

01:38:44;10           Okay, thank you. I just wanted to make sure I was clear. Appreciate it. Thank you.

ALEC MESSINA (IEPA):

01:38:47;03           Thank you.

SEN. DAVID KOEHLER, CHAIR:

01:38:49;26           Senator Biss. And then I-- understand there is a committee-- waiting to-- yes, but this is important and we're gonna take our time and get it done.

SEN. DANIEL BISS:

01:38:56;27           Thanks, Mr. Chairman. I'll be quick. First-- first of all, you mentioned me (LAUGH) and so I feel somewhat compelled to-- re-- respond.

ALEC MESSINA (IEPA):

01:39:05;12           That was a mistake then.

SEN. DANIEL BISS:

01:39:06;08           I mean, I won't respond for long. It'll-- (LAUGH) but you-- you talked about the EPA adjusting some

of its positions recently as an indication of a lack of internal-- clarity and consensus. Let's just remember that, notwithstanding the extraordinary work of-- innumerable scientists and other highly skilled personnel in the rank and file of the EPA, from a leadership perspective, it's being run on behalf of polluters right now.

01:39:35;06

And so that adjustment in position, which God willing will instantly change in January of 2021, is not necessarily reflective of any kind of internal scientific dispute. The question I wanted to ask you is about-- you just said something that piqued my interest and I didn't totally follow it, to be honest. You talked about the self-reporting of stack emissions. What is the role of self-reporting and what's the appropriateness of self-reporting?

ALEC MESSINA (IEPA):

01:40:10;26

So, to your first point, I-- I-- I totally appreciate the importance of what you're saying

in terms of science within U.S. EPA. I-- I am obviously very critical. You know, we're-- we're very fortunate in the-- the front-line EPA-- Illinois EPA staff is very fortunate to be working with those same front-line staff, their counterparts, who have been there, as you well know, for-- for a long period of time.

01:40:31;19

And so-- I-- I think it's understandable and wise to have a healthy level (LAUGH) of skepticism, right. But I would also just add that just because there's skepticism doesn't mean that there aren't legitimate issues that are kind of being worked through. So, I-- I-- I agree with you.

01:40:46;16

(SEN. DANIEL BISS: UNINTEL)

ALEC MESSINA (IEPA):

01:40:48;01

But as to the self-reporting notion-- yes, the company is required-- pursuant to the terms of their construction permit, as well as their ongoing operating permits, there is regular monitoring there as well. But yes, they are

required to-- contract with a-- a third-party vendor who is skilled in the area of conducting stack testing.

01:41:10;25

Illinois EPA and U.S. EPA both reviewed the protocol which was required to be submitted before the stack test occurred to ensure that we were going to get representative numbers. And we were present there to watch that as well. I certainly know that it has-- that-- there has been a lot of questioning of whether a third-party vendor can truly be independent-- and those are questions we h-- have to address all the time, but it's-- it is the nature of this particular business that we work in and that's how that's conducted.

SEN. DANIEL BISS:

01:41:40;19

And-- and so you-- you obviously why a person--

ALEC MESSINA (IEPA):

01:41:42;29

Oh, gosh--

SEN. DANIEL BISS:

01:41:44;04

--naively might have some concern about that.

ALEC MESSINA (IEPA):

01:41:45;06 Absolutely.

SEN. DANIEL BISS:

01:41:45;23 Just for the record, you personally are very confident in the way that process produces--

ALEC MESSINA (IEPA):

01:41:51;15 I-- I personally am confident. And I am also very confident-- you know, I've-- I've-- I've worked at the agency off and on for parts of 20 years and I-- I know the staff personally. I've worked with the staff personally as-- you know, when I was chief counsel before in a previous administration.

01:42:06;21 And I-- I know the staff that-- that reviews the-- these stack test protocols and-- and travels the state on a regular basis to observe and to ensure that there aren't-- that a company isn't playing games, frankly, as they are conducting those tests. And-- and so I have the utmost faith in the agency staff who does that work.

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SEN. DANIEL BISS:

01:42:26;18 Me, too. I guess my question is do you have faith  
in the--

ALEC MESSINA (IEPA):

01:42:29;02 In the contractor?

SEN. DANIEL BISS:

01:42:29;20 --resources that you have and the process to  
ensure that, in fact, games are not being played  
by the contractors and the companies?

ALEC MESSINA (IEPA):

01:42:37;10 No, I think that's a great question. You know,  
we've-- (LONG PAUSE) I will tell you that the  
last two years, it-- it's something that I'm  
proud of, that we've worked very hard to-- to  
fill unfilled positions that have been in place  
for ten-- and I don't know if this is exactly  
your question, Senator, but I think it's p-- at  
least in part.

SEN. DANIEL BISS:

01:43:00;19 It's totally related.

ALEC MESSINA (IEPA):

01:43:01;12 Yeah, so we--

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SEN. DANIEL BISS:

01:43:01;16                   My question is-- is help me-- help me feel  
confident that games are not being played. That's  
my question.

ALEC MESSINA (IEPA):

01:43:06;03                   I-- I-- I have-- yeah, I-- I-- I don't believe  
that. I-- you know, I will tell you, I-- again,  
I-- I know our staff. I-- I-- I've seen them  
testify in court. I've seen them in action. I've--  
- I've actually participated in the training  
that-- that our staff provides to people who  
conduct stack testing throughout the Midwest, and  
I'm-- I'm very confident in their ability.

SEN. DANIEL BISS:

01:43:27;28                   But-- okay, and I-- I don't want-- you were--  
we're out of time. I just wanted to just-- just--  
in case anyone's listening, I'm not questioning  
the ability of your staff. I'm just--

ALEC MESSINA (IEPA):

01:43:34;07                   Yeah.

SEN. DANIEL BISS:

01:43:35;03                   --questioning that we have a system in place that



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makes sure that others aren't playing games--

01:43:37;27

(OVERTALK)

ALEC MESSINA (IEPA):

01:43:38;24

That's why the-- that's why we-- that's why our staff was there, present at that test on both days.

SEN. DANIEL BISS:

01:43:43;11

I hear you. Thank you.

ALEC MESSINA (IEPA):

01:43:44;17

You're welcome. Thank you.

SEN. DAVID KOEHLER, CHAIR:

01:43:45;29

All right. Thank you-- Director, and-- thank you, every, who-- testified or has listened. Thank you, Senator Curran. Thank you, Senator Bush. I know that you have-- facilities in-- in your area as well. Let me just say that-- the House-- had a hearing. They may or may not be bringing something forward-- so we'll wait and see as to whether we take any action-- come two weeks from-- from now when we come back. So-- with that, I'm gonna adjourn the meeting. Thank you.

(BREAK IN TAPE)

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\* \* \*END OF TRANSCRIPT\* \* \*